K053479

510(k) Summary
for
Verify® Dry Heat Label

JUL 18 2006

1. SUBMITTER NAME AND ADDRESS

Richard Bancroft
Albert Browne Ltd., a Subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Contact: Richard Bancroft
Telephone number: 44 116 276 8636

Date Prepared: March 21, 2006

2. DEVICE NAME

Proprietary Name: Verify® Dry Heat Label
Common/Usual Name: Chemical indicator
Classification Name: Physical/Chemical Sterilization Process Indicator

3. PREDICATE DEVICES

- Dry Heat Sterilization Indicator Tape (SPS Medical Supply Corp., K890758)

4. INTENDED USE

The Verify® Dry Heat Label is a process indicator that undergoes a visual color change from amber to black when exposed to dry heat in a temperature range of 160°C to 180°C.

5. DEVICE DESCRIPTION

The proposed Verify® Dry Heat Label consists of indicator ink applied to a substrate using a rotary screen printing method. When exposed to dry heat in the temperature range of 160°C to 180°C the indicator ink changes color from amber to black. The indicator is not intended to indicate that specific sterilization parameters have been met, but simply that the indicator has been exposed to a dry heat process.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Verify® Dry Heat Label indicator and the predicate device are similar. Both the proposed and predicate devices consist of indicator ink applied to a substrate that can be applied to packaged goods prior to dry heat sterilization.

7. PERFORMANCE TESTING

Albert Browne Ltd. has performed testing which demonstrates that the Verify® Dry Heat Label conforms to the applicable requirements of ANSI/AAMI ST60 for Class I process indicators for dry heat sterilization. Additional testing showed that the indicator performed as designed in dry heat sterilization cycles in the range of 160°C to 180°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Albert Browne Limited
C/O Ms. Cynthia J.M. Nolte
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K053479
Trade/Device Name: Verify® Dry Heat Label
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: July 3, 2006
Received: July 3, 2006

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: VERIFY® Dry Heat Label

Indications for Use:

The Verify® Dry Heat Label is a process indicator that undergoes a visual color change from amber to black when exposed to dry heat in a temperature range of 160°C to 180°C.

Prescription Use _______ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __x__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila K Murphey MD 7/18/06

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K053479